



UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE IMPACT INSTRUMENTATION, INC., MODEL 754/754M PORTABLE, SELF-CONTAINED VENTILATION SYSTEM

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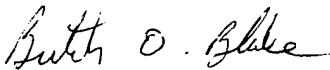
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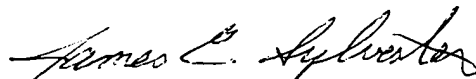
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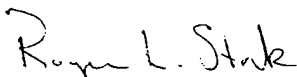
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TESTING AND EVALUATION OF THE IMPACT INSTRUMENTATION, INC., MODEL 754/754M PORTABLE, SELF-CONTAINED VENTILATION SYSTEM

BACKGROUND

The Air Force Medical Logistics Office requested the Air Force Medical Equipment Development Laboratory (AFMEDL) participation in evaluating and approving the Impact Instrumentation, Inc., Model 754/754M, Portable, Self-Contained Ventilation System for use on board USAF aeromedical evacuation aircraft. Specific components of the Impact Instrumentation Inc., Model 754/754M, Portable, Self-Contained Ventilation System that underwent the evaluation process included: the Impact model 754/754M basic unit (P/N: 800-0754-01); (S/N: 9611003); disposable patient breathing circuit (P/N: 820-0067-00); transport case (P/N: 402-0005-00) and the multivoltage power supply (P/N: 703-0754-09) / (S/N: 980501X). All components of the model 754/754M were tested for airworthiness. Throughout this report, the term Equipment Under Test (EUT) refers to the model 754/754M.

DESCRIPTION

The EUT is a portable, electronically controlled ventilator with an integral compressor and air/oxygen mixer. It's microprocessor controls EUT functions, displays airway pressure, alarm parameters, gas source(s) & flows, gas blending and power signals. Assist Control, Spontaneous Intermittent Mandatory Ventilation, and Continuous Positive Airway Pressure modes can be operated with or without Positive End Expiratory Pressure (PEEP) and with or without mandatory ventilations. All modes are PEEP and altitude compensated to minimize patients breathing effort. EUT can mix and deliver blended gases from 21-100% oxygen using internal or external source(s). The unit operates off of 115 VAC/60 & 400 Hz, 28 VDC, and internal rechargeable battery. The unit weighs approximately 13 lbs. Its dimensions are 8.87 in. W. X 11.5 in. H. X 4.5 in. D. The power supply is 1.88 in. W. X 2.75 in. H. X 8.5 in. D. and weighs 4.16 lbs. (Figure 1).

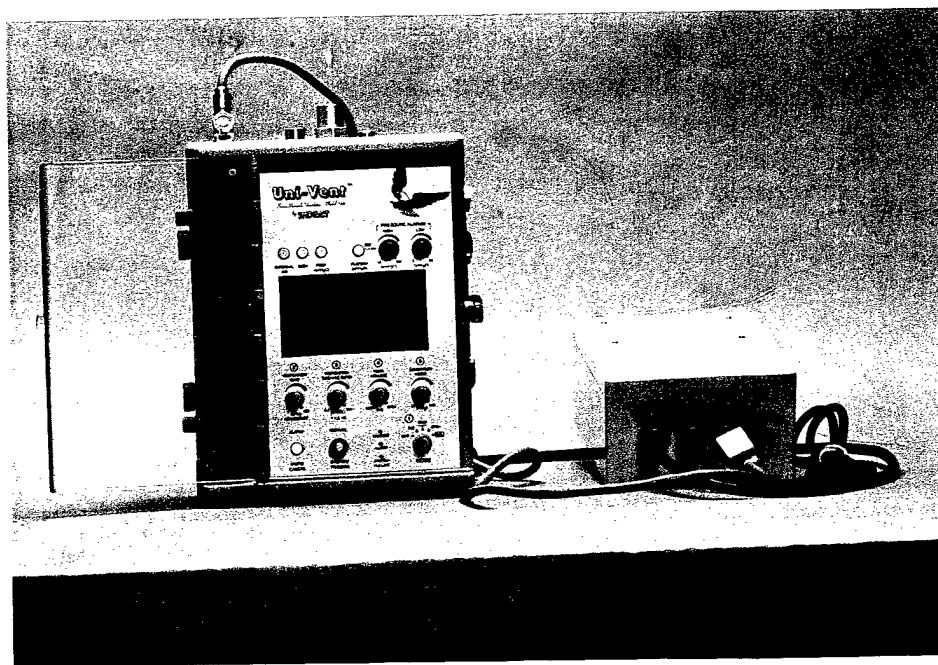


Figure 1. Impact Instrumentation, Inc., Model 754/754m, Portable, Self-Contained Ventilation System

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 2), military standards (3-8), and manufacturer's literature (9). The AFMEDL Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check was developed specific to this EUT to verify its proper functioning under various testing conditions. All tests were conducted by AFMEDL personnel assigned to the Systems Research Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas, unless otherwise noted.

The EUT was subjected to various laboratory and in-flight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection
2. Vibration
3. Electromagnetic Interference (EMI)

4. Thermal/ Humidity Environmental Conditions, encompassing:

- a. Hot Operation
- b. Cold Operation
- c. Humidity Operation
- d. Hot Temperature Storage
- e. Cold Temperature Storage

5. Hypobaric Conditions

- a. Cabin Pressure/Altitude
- b. Rapid Decompression to simulated flight level

6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

- a. The EUT was inspected for quality of workmanship, production techniques and pre-existing damage.
- b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1); AFI 41-203, Electrical Shock Hazards (3); AFI 41-201, Equipment Management in Hospitals (4). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz and 115 VAC/400 Hz.
- c. The EUT was examined to ensure it met basic requirements for human factor design as outlined in MIL-STD 1472 (5).
- d. A test setup and performance check was developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The EUT was prepared for tests as follows:

- 1. Place EUT on a level surface
- 2. Place a Rp 20 resistor and/or dial a resistance of 20 on the patient lung simulator
- 3. Connect patient end of breathing circuit to patient lung simulator

4. Connect other end of patient circuit to appropriate outlets on EUT
5. Select desired power source (115 VAC/60 or 400 Hz, 28 VDC, or internal battery)
6. Select settings on EUT of 16 breaths per minute (bpm), 800 milliliters (mls) tidal volume, I:E ratio 1:2; set compliance on patient lung simulator to 0.05
7. Turn unit on by rotating the "mode" knob to "cal" and waited for EUT to perform a self-test
8. Self-test complete, rotated "mode" knob back to desired operation mode (A/C, SIMV, or CPAP). The display screen will verify parameter inputs.

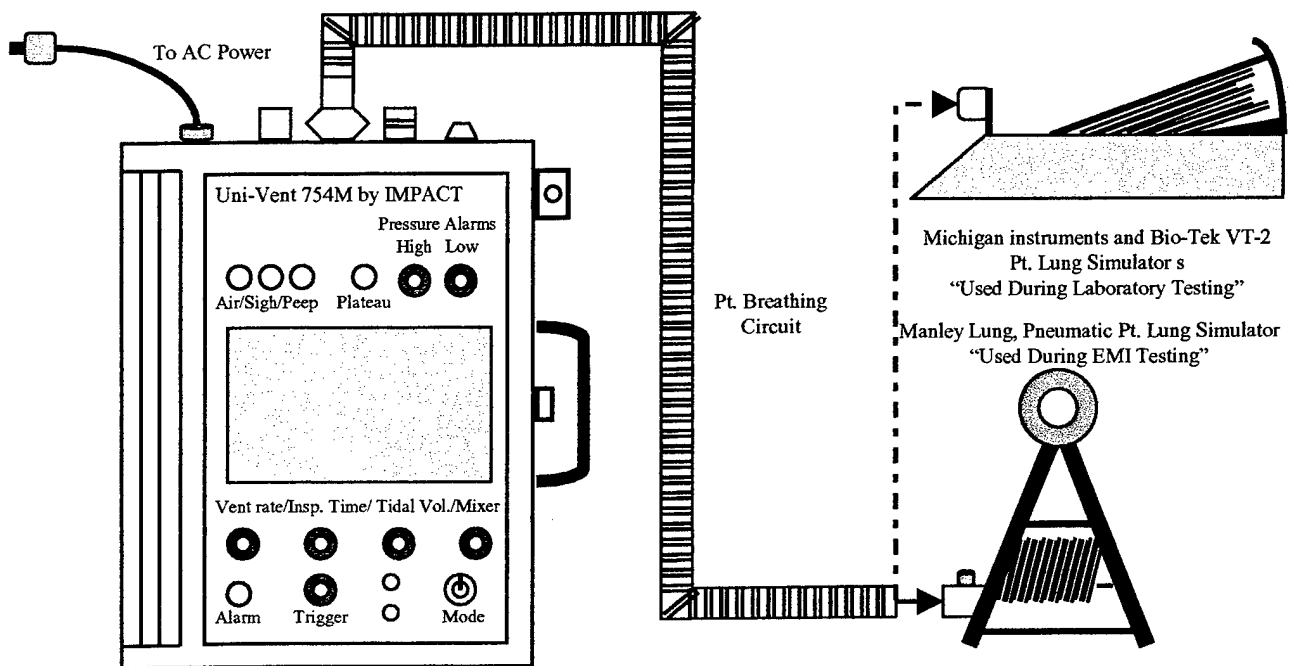


Figure 2. Test Setup

PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT during each of the following test conditions: Connect patient-end of breathing circuit to patient lung simulator and connected other end of patient circuit to appropriate outlets on EUT. Configure the EUT and simulator IAW TEST SETUP. Rotate "mode" knob on EUT to "cal" and wait for EUT to perform a self-test. With self-test complete rotate "mode" knob back to desired operation mode (A/C, SIMV, or CPAP). The screen will show selected parameters and EUT operational characteristics. Operational data was recorded three times at one-minute intervals for trend analysis.

Battery Operation as outlined in Impact Instruments Inc., Operation Manual (9)

VIBRATION

Vibration testing is critical to determine, "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (6). Testing was conducted on a Unholtz-Dickey Corporation Vibration Test System, amplifier model SA30 and shaker model R16W. This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. The EUT was secured to an aircraft stanchion pole segment, using a mounting bracket provided by manufacturer. The stanchion pole segment with the EUT was secured to the vibration table as it would be secured in the aircraft (Figure 3). The EUT was subjected to vibration curves with similar intensities and durations as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

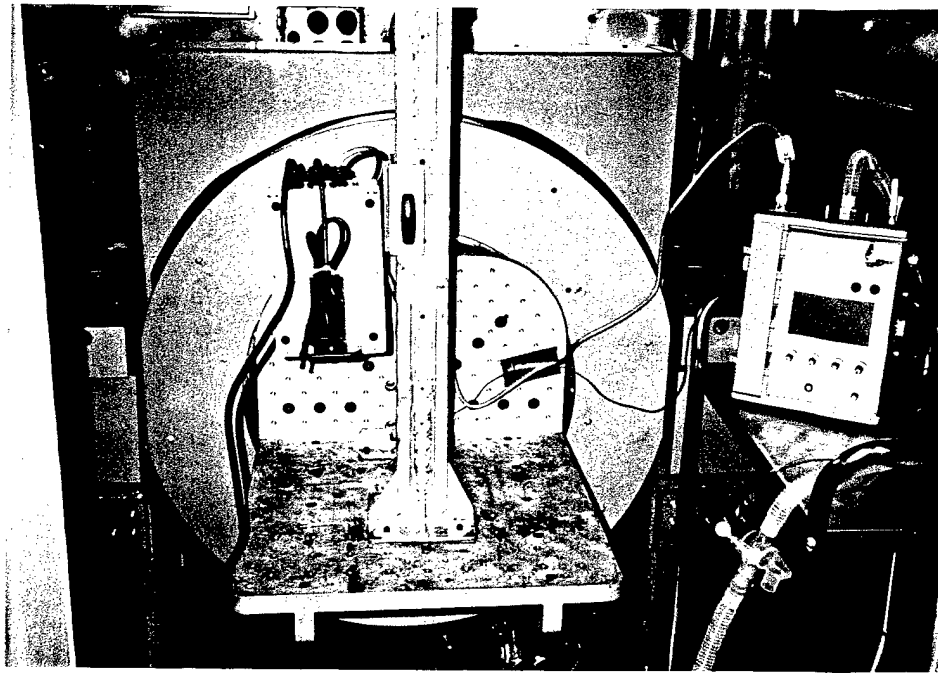


Figure 3. Vibration Table Mounting

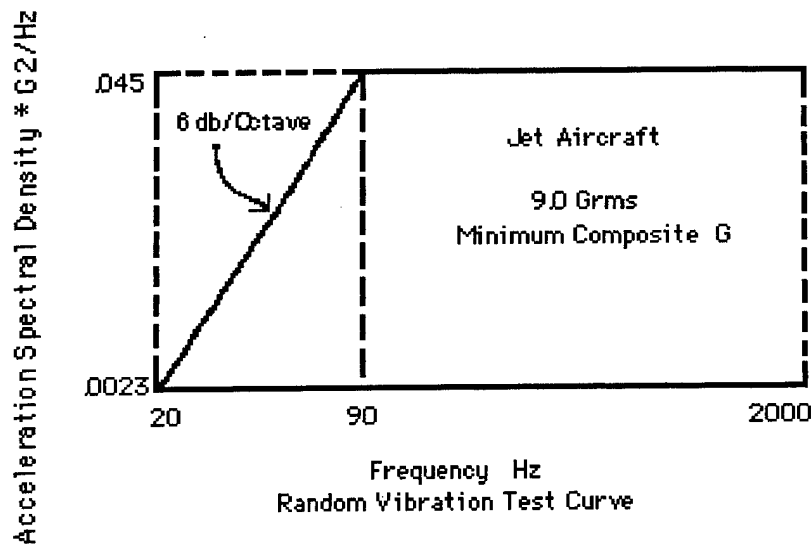
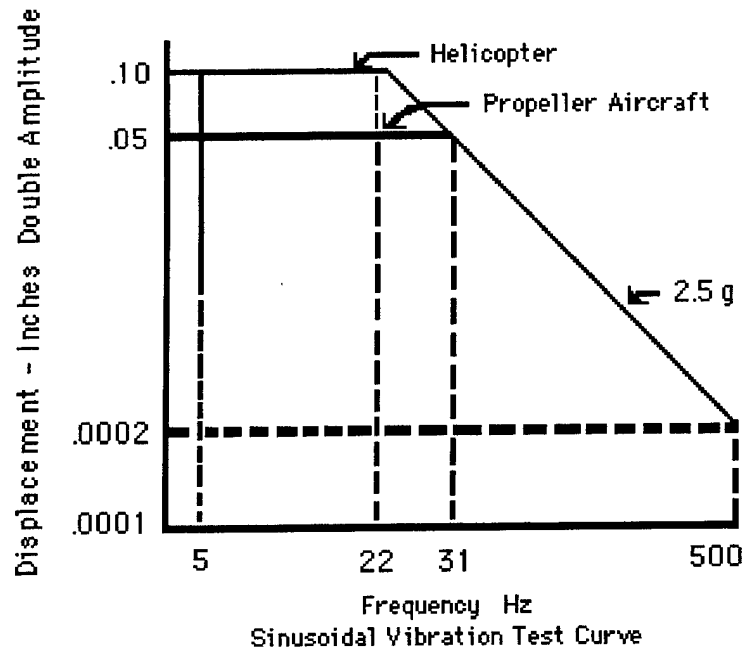


Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility is a primary concern for equipment to be used safely on USAF aeromedical evacuation aircraft. Emissions from medical equipment may cause

electromagnetic interference (EMI) with potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD-461D & MIL-STD-462D (7 & 8). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the EUT during operation. It verifies the EUT's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were measured throughout the entire band of 10 kHz - 10 MHz. This test measured emissions generated by the EUT along its power supply lines. It was performed to assess the EUT's potential to affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (MIL-STD-461D field strength values from Table IV, Category Aircraft Internal). This test evaluated the EUT's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

e. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

f. Conducted Susceptibility (CS-116), "Conducted Susceptibility, Damped Sinusoidal Transients, Cables and Power Leads, 10 kHz - 100 MHz," respectively. The "basic concept of this test is to simulate electrical current and voltage waveforms occurring in platforms from excitation of natural resonances."

During emissions testing, all EUT's electrical components were operating for the duration of the test to create the worst case emissions scenario. In these tests, the EUT was programmed to provide 16 bpm, 800 mls tidal volume, I:E ratio 1:2 and mode in A/C. For both emissions and susceptibility testing, the EUT was tested for operation using 115 VAC/60 and 400 Hz, 28 VDC, and internal battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance (6). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, corrosion, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in a calibrated Thermotron Industry, model SM-32 environmental chamber. The EUT was placed in the center of the environmental chamber. All input and output cables, wires, and patient breathing circuit were routed through ports in the chamber wall, which were subsequently sealed with precut sponge plugs. The other components of the test setup remained outside the chamber. For operational tests, the EUT was monitored continuously, and a performance check was conducted every 15 minutes. For storage tests, the EUT was placed in the chamber and remained non-operational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

- a. Humidity: $94 \pm 4\%$ RH, $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 4 hr
- b. Hot Temp Operation: $120^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($49^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 2 hr
- c. Cold Temp Operation: $32^{\circ}\text{F} \pm 7.2^{\circ}\text{F}$ ($0^{\circ}\text{C} \pm 4^{\circ}\text{C}$) for 2 hr
- d. Hot Temp Storage: $140^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($60^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hr
- e. Cold Temp Storage: $-40^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($-40^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hr

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on operation of the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation pressurizes cabin atmosphere to barometric pressures equivalent to 8,000 - 15,000 ft above sea level. Altitude testing consisted of operating the EUT while ascending from ground level to 15,000 ft, stopping at 2,000 ft increments for performance checks. The rates of ascent and descent were 5,000 ft/min.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressure. It is important to assess medical equipment functioning during and after RD so as not to endanger patients, personnel, or the aircraft. The EUT operated inside the rapid decompression test chamber as the chamber depressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few minutes, and then returned to ground at a rate of 10,000 - 12,000 ft/min. The test was repeated twice more, once for a 7-second RD and once for a 1-second RD. The EUT was monitored throughout the series of decompressions. Performance checks were assessed each time the EUT returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability of medical equipment items under actual operating conditions. In-flight test and analysis demonstrates the EUT's ability to provide patient care on board USAF aircraft. Safe and reliable operation is the primary goal of the in-flight evaluation and forms the basis for subsequent recommendations to the users.

Flight qualified AFMEDL aeromedical crewmembers flying on C-141 aeromedical evacuation missions conducted this phase of testing. The EUT was positioned and secured to an aircraft stantion pole using the mounting bracket provided by the manufacturer and/or on a NATO litter using litter straps and litter equipment brackets. Then human factor characteristics were evaluated, e.g., securing methods, setup/tear down times and securing locations. Feedback from other aeromedical evacuation crewmembers was obtained concerning EUT human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits. Battery Endurance revealed operation time well within manufacturer's specifications. The battery operated the EUT between 2.2 & 2.7 hours before the battery low indicator came on indicating 30 minutes of battery life left. Between 2.5 & 3.1 hours of operation, the EUT failed to operate turning itself off and the liquid crystal display (LCD) went blank.

VIBRATION

During evaluation, the EUT was programmed to maintain 16 bpm, 800 mls tidal volume, I:E ratio 1:2 and mode in assist control to assess the EUT's ability to function without the possibility of system failure. The unit performed according to manufacturer's specifications and AFMEDL guidelines without any system failure or malfunction.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAI, Wright-Patterson AFB certified the EUT for use in aeromedical evacuation system on all U.S. Air Force aircraft (including small and large body, fixed and rotary wing) while operating from 115 VAC/60 & 400 Hz, 28 VDC, and internal battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT experienced problems during humidity testing. The EUT would interpose a sigh at four breath intervals without the sigh mode engaged. The EUT would also show an increase in breath rate, swings in tidal volume and display a numerical failure to operate code. After removing the unit from a humidified environment the EUT returned to normal operation. The company was contacted and the EUT sent back for modifications and returned to AFMEDL. The EUT was exposed to the Panamanian climate on a C-141 aeromedical evacuation mission that remained overnight in country. On day two the EUT experienced similar behavior as was noted during laboratory testing. The company was notified and the EUT was sent back for further development and modification to the thermal circuit that controls unit operation. Upon return to AFMEDL, the EUT was subjected to a new set of environmental evaluations and in-flight testing. The EUT operated according to AFMEDL and manufacturer's guidelines during all five phases of testing.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing. The unit was able to maintain 16 bpm, 800 mls tidal volume, I:E ratio 1:2 and mode in assist control without system failure up to 15,000 ft cabin altitude.
2. Rapid Decompression: The EUT operated satisfactorily following each rapid decompression event.

AIRBORNE PERFORMANCE

The in-flight evaluation of the EUT was performed on two separate C-141 aeromedical

evacuation missions. Second day of the first evaluation the EUT experienced a failure code that could not be cleared by AFMEDL personnel. The EUT was sent back to the company for modification. The second evaluation following EUT modifications confirmed that the unit would operate successfully during all phases of flight. Analysis of performance data indicated this unit was easy to enplane and deplane. The EUT was secured to a NATO litter using litter straps and litter equipment brackets. During evaluation it was determined that manufacturer's mounting bracket does not work on center, line station poles, but will work on the side wall station poles on C-141 aircraft. Considerations include limitations on hearing audible alarms with hearing protection on. Crewmembers must rely on visual prompts, which could be viewed up to 3 feet away.

SUMMARY

AFMEDL found the Impact Instrumentation, Inc., Model 754/754M, Portable, Self-Contained Ventilation System to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft while operating from 115 VAC/60 & 400 Hz, 28 VDC, and internal battery power. See following recommendations listed below. Its operation was within expected parameters when subjected to electromagnetic interference (EMI), environmental extremes, simulated cabin altitudes. It did not produce a hazard to patient or crew during rapid decompression. The following recommendations apply:

- a. In certain aircraft such as the C-130/C-141 the manufacturer's mounting bracket does not work on center line station poles, only the side-wall station poles. Recommend modifications to mounting bracket enhancing universal capability across all aircraft.
- b. Crewmembers were limited on their ability to hear audible alarms in flight when wearing hearing protection. Crewmembers must rely on visual prompts that are viewable with proper placement up to 3 feet away.
- c. To correct problems seen during thermal/humidity environmental conditions and airborne performance, the manufacturer had to reprogram the null circuit to compensate for environmental extremes. This modification must be implemented in all units used in the aeromedical arena.

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
2. Emergency Care Research Institute (ECRI)
3. AFI 41-203, Electrical Shock Hazards
4. AFI 41-201, Equipment Management in Hospitals
5. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
6. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
7. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
8. MIL-STD-462 D, Measurement of EMI Characteristics.
9. Impact Instrumentation, Inc., Model 754/754M, Portable, Self-Contained Ventilation System, Operation Manual.
10. AFMEDL Procedures Guide, Internal Operating Instruction, Systems Research Branch, Air Force Research Laboratory.

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF
IMPACT INSTRUMENTATION, INC., MODEL 754/754M
PORTABLE, SELF-CONTAINED VENTILATION SYSTEM

SPECIFICATIONS

General

Size: (Vent System)	8.87 in. W. X 11.5 in. H. X 4.5 in. D.
(Pwr. Supply)	1.88 in. W. X 2.75 in. H. X 8.5 in. D.
Weight:	
(Vent System)	13 lbs.
(Pwr. Supply)	4.16 lbs.
Operating Modes:	Assist Control, Spontaneous Intermittent Mandatory Ventilation, Continuous Positive Airway Pressure.
Flow Rate:	0 – 60 lpm. (Adjustable)
Power:	
(Vent System)	11-15 VDC, (Negative ground)
(Pwr. Supply)	115 VAC/60 & 400 Hz, 28 VDC, and internal rechargeable battery.
Operating time:	Internal batteries: 3 hours, maximum internal compressor 12 hours using external gas source External AC: Continuous External DC: Continuous
Environmental	Temperature: -60°C to 60°C (operating). 10°C to 30°C (storage temperature). -20°C to 50°C (charging)